

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>		
				Application Number	10/626,943	
				Filing Date	July 25, 2003	
				First Named Inventor	Rubino	
				Art Unit	1614	
Examiner Name	G. Polansky					
Sheet	1	of	5	Attorney Docket Number	AM100802	

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	19	US-5,674,874	10-07-1997	Huasheer	
	20	US-6,022,852	02-08-2000	Klokkers	
	21	US-6,193,985	02-27-2001	Sonne	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	22	WO 99/56727	11-11-1999	Ramtoola		
	23	WO 97/22358	06-26-1997	Sherman		

Examiner Signature	Date Considered
--------------------	-----------------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional).

<sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/626,943
				Filing Date	July 25, 2003
				First Named Inventor	Rubino
				Art Unit	1614
				Examiner Name	G. Polansky
				Attorney Docket Number	AM100802
Sheet	2	of	5		
<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T <sup>2</sup>
	24	"Oxidation Inhibitor" in Römpp Lexikon Chemie, 10 <sup>th</sup> Ed., Falbe and Regitz, Eds., Georg Thieme Verlag, Stuttgart, Germany: 1996, page 229			
	25	Machine translation of "Oxidation Inhibitor" in Römpp Lexikon Chemie, 10 <sup>th</sup> Ed., Falbe and Regitz, Eds., Georg Thieme Verlag, Stuttgart, Germany: 1996, page 229			
	26	"Butylated Hydroxyanisole" in Römpp Lexikon Chemie, 10 <sup>th</sup> Ed., Falbe and Regitz, Eds., Georg Thieme Verlag, Stuttgart, Germany: 1996, page 423			
	27	Machine translation of "Butylated Hydroxytoluene" in Römpp Lexikon Chemie, 10 <sup>th</sup> Ed., Falbe and Regitz, Eds., Georg Thieme Verlag, Stuttgart, Germany: 1996, page 423			
	28	"Citric Acid" in Römpp Lexikon Chemie, 10 <sup>th</sup> Ed., Falbe and Regitz, Eds., Georg Thieme Verlag, Stuttgart, Germany: 1996, page 759-760			
	29	Machine translation of "Citric Acid" in Römpp Lexikon Chemie, 10 <sup>th</sup> Ed., Falbe and Regitz, Eds., Georg Thieme Verlag, Stuttgart, Germany: 1996, page 759-760			
	30	"Tocopherol" in Römpp Lexikon Chemie, 10 <sup>th</sup> Ed., Falbe and Regitz, Eds., Georg Thieme Verlag, Stuttgart, Germany: 1996, page 4572-4573			
	31	Machine translation of "Tocopherol" in Römpp Lexikon Chemie, 10 <sup>th</sup> Ed., Falbe and Regitz, Eds., Georg Thieme Verlag, Stuttgart, Germany: 1996, page 4572-4573			
	32	"Added Substances (Excipients) in Parenteral Formulations" in Modern Pharmaceuticals, 4 <sup>th</sup> Ed., Banker & Rhodes, Eds., Marcel Dekker Inc.: New York, NY, July 4, 2002, pages 388-393			
	33	"Added Substances" in Pharmaceutical Dosage forms and Drug Delivery Systems, 7 <sup>th</sup> Ed., Ansel et al., Eds., Lippincott Williams and Wilkins: Philadelphia, PA, 1999, pages 405-406			
	34	"Citric Acid Monohydrate" in Handbook of Pharmaceutical Excipients, 3 <sup>rd</sup> Ed., Kibbe, Ed., American Pharmaceutical Association: Washington, DC, 2000, pages 140-141			
Examiner Signature				Date Considered	

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional).

<sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/626,943
Filing Date	July 25, 2003
First Named Inventor	Rubino
Art Unit	1614
Examiner Name	G. Polansky
Attorney Docket Number	AM100802

Sheet	3	of	5
-------	---	----	---

### NON PATENT LITERATURE DOCUMENTS

[illegible]

**Examiner  
Signature**

Date  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional).

<sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/626,943
Filing Date	July 25, 2003				
First Named Inventor	Rubino				
Art Unit	1614				
Examiner Name	G. Polansky				
Attorney Docket Number	AM100802				
Sheet	4	of	5		
<b>OTHER INFORMATION SUBMITTED FOR CONSIDERATION BY THE OFFICE</b> <b>(37 CFR §1.98(a)(1))</b>					
Examiner Initials*	Cite No. <sup>1</sup>	For unpublished applications, include the name of the inventor (in CAPITAL LETTERS), US serial number, and filing date.			T <sup>2</sup>
	37	Office Action issued in Australian Patent Application No. 2003254168 on June 2, 2008			
	38	Correspondence from the Chilean associate with an informal English translation of a first Office Action issued in Chilean Patent Application No. 1490-2003 in 2006			
	39	Correspondence from the Chilean associate with an informal English translation of a second Office Action issued in Chilean Patent Application No. 1490-2003 in 2008			
	40	Correspondence from the Chilean associate with an informal English translation of a third Office Action issued in Chilean Patent Application No. 1490-2003 in 2009			
	41	English translation of a first Office Action issued in Colombian Patent Application No. 05-017.056 on August 26, 2009			
	42	English translation of a second Office Action issued in Colombian Patent Application No. 05-017.056 on February 4, 2009			
	43	English translation of an Opposition filed by the Association of Pharmaceutical Laboratories in Ecuador Patent Application No. SP-05-5628 in 2005			
	44	English translation of a first Office Action issued in Russian Federation Patent Application No. 2005105301 on May 23, 2007			
	45	English translation of a second Office Action issued in Russian Federation Patent Application No. 2005105301 on October 30, 2007			
	46	English translation of a second Office Action issued in Vietnam Patent Application No. 1-2005-00241 on January 11, 2007			
	47	Response to Oppositions filed in European Patent Application No. 03771828.5 on June 30, 2009			
	48	Summons to Attend Oral Proceedings issued in European Patent Application No. 03771828.5 on September 17, 2010			
Examiner Signature		Date Considered			

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional).

<sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/626,943
Filing Date	July 25, 2003				
First Named Inventor	Rubino				
Art Unit	1614				
Examiner Name	G. Polansky				
Attorney Docket Number	AM100802				
Sheet	5	of	5		
<b>OTHER INFORMATION SUBMITTED FOR CONSIDERATION BY THE OFFICE (37 CFR 51.98(a)(1))</b>					
Examiner Initials*	Cite No. <sup>1</sup>	For unpublished applications, include the name of the inventor (in CAPITAL LETTERS), US serial number, and filing date.			
	49	Teva's Response dated November 23, 2010 to the Summons to Attend Oral Proceedings issued in Europe Patent Application No. 03771828.5 on September 17, 2010			
	50	Wichmann's Response dated November 24, 2010 to the Summons to Attend Oral Proceedings issued in Europe Patent Application No. 03771828.5 on September 17, 2010 and English translation thereof			
	51	Written Submissions for Oral Proceedings filed by Applicant in European Patent Application No. 03771828.5 on December 13, 2010			
	52	Official Communication of Revocation of Patent issued in European Patent Application No. 03771828.5 on dated March 1, 2011			
Examiner Signature				Date Considered	

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional).

<sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.